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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,114	06/22/2001	Seung-Ho Choi	19916-003001	9054

26161 7590 09/14/2006

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,114

Applicant(s)

CHOI ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-22 and 42 is/are pending in the application.
- 4a) Of the above claim(s) 6-11 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,12,14-22 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 2, 3, 5-22, and 42 are pending in the application.
2. In the prior action, the Final action mailed on February 22, 2006, claims 2, 3, 5-22, and 42 were pending; with claims 2, 3, 5, 12, 14-22, and 42 under consideration and rejected; and claims 6-11, and 13 withdrawn as to non-elected inventions.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 22, 2006 has been entered.

In this submission, the Applicant amended claims 2 and 5.

4. Claims 2, 3, 5, 12, 14-22, and 42 are currently under consideration.

Specification

5. **(Prior Objection- Withdrawn)** The disclosure was objected to because the applicant referred to the cephalosporin "cefzoprane" instead of - - cefozopran- -. In view of the amendment, the objection is withdrawn.

Claim Objections

6. **(Prior Objection- Withdrawn)** Claim 5 was objected to for referring to "cefzoprane" instead of - - cefozopran- -. In view of the amendment, the objection is withdrawn.

7. **(New Objection- Necessitated by Amendment)** Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This claim reads in part on embodiments wherein the cephalosporin of claim 2 is a combination of cephalosporins. However, claim 2 requires that the antimicrobial agent of the claim “consist[s] of a cephalosporin.” Thus, claim 2 requires the presence of one, and only one such molecule, and therefore excluded the combinations permitted by claim 5.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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9. **(Prior Rejection- Restated and Maintained)** Claims 2, 3, 5, 12, 14-22, and 42 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8-11, 14-21, 24, 31, and 32-34 of U.S. Patent No. 6,248,360. The Applicant traverses the rejection on the basis that the claims of the copending application do not teach or suggest the inclusion of an absorption enhancer. In view of the argument, the rejection is restated as a rejection of claims 2, 3, 5, 12, 14-22, and 42 for obviousness type double patenting over claims 1, 8-11, 14-21, 24, 31, and 32-34 of U.S. Patent No. 6,248,360 in view of Watts (WO 98/30207). As was previously described, Watts also teaches compositions for the oral administration of therapeutics. The reference teaches that "[i]t is well known in the literature that the absorption of polar molecules across mucosal membranes may be greatly improved if they are administered in combination with so-called "absorption enhancers." Page 3, lines 15-17. Thus, it would have been obvious to those of ordinary skill in the art to include such compounds in the compositions of claimed by the '360 patent so as to achieve the additional absorption. Thus, the present claims represent obvious variants of the previously claimed inventions. The rejection is therefore maintained as restated for the reasons above and the reasons of record.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. **(Prior Rejection- Maintained)** Claims 2, 3, 5, 12, 14-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al., U.S. Patent 6,458,287, in view of Watts. The rejection is restated such that the claims are rejected over Scott in view of Watts et al. (WO 98/30207). The Applicant traverses the rejection on the basis that the claims have been amended to read on a composition comprising “an antimicrobial agent consisting of a cephalosporin,” and that the Scott reference teaches that in order for such cephalosporin agents to be incorporated into the microparticles, they are first attached to a macromolecule. The Applicant asserts that the closed language of the claims excludes embodiments wherein the drug is so attached. This argument is not found persuasive.

The claims read on a composition *comprising* a antimicrobial agent, wherein the antimicrobial agent *consists* of the cephalosporin. Thus, while the claim provides closed language with respect to the antimicrobial agent used, it is not closed with respect to other constituents of the claimed composition. The amended claim language therefore does not exclude the use of the macromolecules of Scott, which are not themselves antimicrobial agents. The rejection is therefore maintained for the reasons above, and the reasons of record.

12. **(Prior Rejection- Maintained)** Claims 2, 3, 5, 12, 14-22, and 42 were rejected under 35 U.S.C. 103(a) as being unpatentable over Scott in view of Watts as applied to claims 2, 3, 5, 12, 14-22 above, and further in view of Horwitz et al. (U.S. 5,783,561). The Applicant traverses this rejection for the same reasons as indicated with respect to the rejection above. These arguments are not found persuasive for the same reasons as indicated above. The rejection is therefore maintained for those reasons, and the reasons of record.

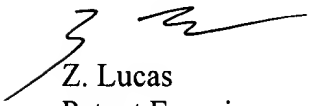
Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner